olaparib (Lynparza®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO048

Description

Olaparib (Lynparza) is an orally administered poly (ADP-ribose) polymerase (PARP) enzymes inhibitor including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular homeostasis, such as DNA transcription, cell cycle regulation, and DNA repair.

Length of Authorization

- Initial:
  i. Early, high-risk breast cancer: 12 months
  ii. All other indications: 3 months
- Renewal:
  i. Early, high-risk breast cancer: no renewals allowed
  ii. All other indications: 12 months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
olaparib (Lynparza)	Breast cancer, early, high-risk, HER2-negative, germline BRCA-mutated (gBRCAm), after neoadjuvant or adjuvant chemotherapy; Breast cancer, metastatic, HER2-negative, gBRCAm with prior chemotherapy in the metastatic setting; Ovarian, fallopian tube, or primary peritoneal cancer; advanced, homologous recombination deficient (HRD)-positive status; after complete or partial response to first-line platinum chemotherapy, in combination with bevacizumab; maintenance therapy;	100 mg tablets	120 tablets/30 days

	Ovarian, fallopian tube, or primary peritoneal cancer; gBRCAm or sBRCAm, after first-line platinum-based chemotherapy, first-line maintenance therapy; Ovarian, fallopian tube, or primary peritoneal cancer; recurrent after complete or partial response to platinum-based chemotherapy; maintenance therapy Pancreatic adenocarcinoma, metastatic gBRCAm or sBRCAm; first-line maintenance therapy in those who have not progressed on at least 16 weeks of first-line platinum-based chemotherapy; Prostate cancer, metastatic castration-resistant, homologous recombination repair (HRR) gene-mutated Prostate cancer, metastatic castration-resistant, deleterious or suspected deleterious BRCA-mutated (BRCAm)	150 mg tablets	120 tablets/30 days

Initial Evaluation

I. **Olaparib (Lynparza)** may be considered medically necessary when the following criteria below are met:
   A. Prescribed by, or in consultation with, a specialist in oncology; **AND**
   B. The patient has <u>not</u> progressed on or after prior PARP inhibitor therapy (e.g., olaparib [Lynparza], niraparib [Zejula], rucaparib [Rubraca], talazoparib [Talzenna]); **AND**
   C. A diagnosis of one of the following:
      1. **Ovarian cancer (including fallopian tube and primary peritoneal cancer)**; **AND**
         i. The member has advanced or metastatic (Stage III-IV) disease; **AND**
         ii. Request is for <u>maintenance therapy</u>**; AND**
            a. Member has completed a prior platinum-based chemotherapy regimen (e.g., cisplatin, carboplatin, oxaliplatin); **AND**
            b. The tumor is platinum-sensitive (i.e., the patient is in complete or partial response to their most recent platinum-based regimen); **AND**
            c. Documentation of deleterious (pathogenic) or suspected deleterious (likely pathogenic) BRCA mutations (gBRCAm or sBRCAm); **AND**
               i. For <u>first-line maintenance therapy</u>:

1. Olaparib (Lynparza) will be used as monotherapy; **AND**
    a. Member has not received prior treatment with bevacizumab; **OR**
2. Member has received, and currently has a positive response to bevacizumab treatment; **AND**
    a. Documentation of deleterious (pathogenic) or suspected deleterious (likely pathogenic) homologous recombination deficient-positive mutation (gHRDm); **AND**
    b. Olaparib (Lynparza) will continue to be used in combination with bevacizumab; **OR**

ii. Request is for maintenance therapy for recurrent disease after at least two prior lines of platinum-based (e.g., cisplatin, carboplatin, oxaliplatin) chemotherapy regimens

2. **Breast cancer, early, high-risk or metastatic; AND**
    i. Member has a diagnosis of HER2-negative breast cancer; **AND**
    ii. Documentation of deleterious (pathogenic) or suspected deleterious (likely pathogenic) gBRCAm; **AND**
    iii. Diagnosis of early (stage II-III) breast cancer; **AND**
        a. Provider attestation that member is at high risk of disease recurrence; **AND**
        b. Has required surgical intervention; **AND**
        c. Has received prior adjuvant or neoadjuvant therapy with a taxane (e.g., docetaxel), an anthracycline (e.g., doxorubicin), or platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin); **AND**
        d. Olaparib (Lynparza) will be used as monotherapy or in combination with endocrine therapy (e.g., anastrozole, tamoxifen, fulvestrant); **OR**
    iv. Diagnosis of metastatic (stage IV) breast cancer; **AND**
        a. Has received prior treatment with an anthracycline (e.g., doxorubicin); **AND**
        b. Has received prior treatment with a taxane (e.g., paclitaxel); **AND**
        c. Member has disease progression on at least one prior endocrine therapy; **OR**
            i. Endocrine therapy has been deemed inappropriate by the treating healthcare provider; **AND**

d. Medication will not be used in combination with other anti-cancer agents; **OR**

3. **Pancreatic cancer, First-line Maintenance; AND**
   i. Documentation of deleterious (pathogenic) or suspected deleterious (likely pathogenic) gBRCAm; **AND**
   ii. Diagnosis of metastatic pancreatic adenocarcinoma; **AND**
   iii. The member has received at least 16 weeks of continuous treatment with a platinum-based chemotherapy regimen (e.g., cisplatin, carboplatin, oxaliplatin) that was administered as first-line therapy; **AND**
   iv. Provider attests that the disease has not progressed while on first-line platinum-based chemotherapy regimen (e.g., cisplatin, carboplatin, oxaliplatin); **AND**
   v. Medication will not be used in combination with other anti-cancer agents; **OR**
4. **Prostate cancer, metastatic, castration-resistant (mCRPC); AND**
   i. Documentation of metastatic disease (i.e., stage IV); **AND**
   ii. Disease is castration-resistant, defined by disease progression despite ongoing therapy with a gonadotropin-releasing hormone analog (GnRH) or a bilateral orchiectomy; **AND**
   iii. The request is for olaparib (Lynparza) in combination with abiraterone (Zytiga, Yonsa) and prednisone or prednisolone (Note: the plan's preferred therapy is generic abiraterone unless contraindicated or not tolerated); **AND**
      a. The member has not had disease progression on a second-generation antiandrogen agent (e.g., abiraterone (Zytiga, Yonsa), enzalutamide (Xtandi), apalutamide (Erleada), darolutamide (Nubeqa)); **AND**
      b. Documentation of deleterious (pathogenic) or suspected deleterious (likely pathogenic) gBRCAm; **OR**
   iv. The request is olaparib (Lynparza) monotherapy; **AND**
      a. Documentation of deleterious (pathogenic) or suspected deleterious (likely pathogenic) alteration in at least **one** of the following HRR genes: ATM, BRCA1, BRCA2; **AND**
      b. Disease has progressed on prior enzalutamide (Xtandi) or abiraterone (Zytiga, Yonsa) treatment.

II. Olaparib (Lynparza) is considered investigational when used for all other conditions, including but not limited to:

A. Early breast cancer with low-moderate-risk without metastasis, and/or HER2-positive, and/or breast cancer without gBRCAm
B. Treatment of early, high-risk breast cancer for > 12 months
C. Pancreatic cancer without metastasis, and without gBRCAm
D. Metastatic, gBRCAm pancreatic cancer that has progressed on first line platinum-based chemotherapy
E. Metastatic, castration-resistant prostate cancer with a tumor mutation NOT listed above (including BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L) when used as a subsequent-line treatment
F. Use after disease progression on or after prior PARP inhibitor therapy
G. Treatment of advanced ovarian cancer after 3 or more lines of therapy

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Olaparib (Lynparza) will not be used in combination with other anti-cancer agents (outside of gonadotropin-releasing hormone agonist [e.g., leuprolide] or endocrine therapy [e.g., anastrozole, tamoxifen, fulvestrant] or bevacizumab or abiraterone); **AND**
IV. Clinical documentation of response to treatment (e.g., stabilization of disease or decrease in tumor size, or tumor spread).

Supporting Evidence

I. Many treatment options exist for ovarian, breast, pancreatic, and prostate cancer. Initial and subsequent therapies in this setting are contingent upon patient-specific characteristics. Given the complexities surrounding the diagnosis and treatment options, targeted drug therapies, such as PARP inhibitors, should be prescribed by, or in consultation with, an oncologist.
II. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy to support the use of a subsequent PARP inhibitor following the progression of disease on another PARP inhibitor.
III. **Treatment of Ovarian Cancer:**
- In the pivotal trials for maintenance treatment of recurrent ovarian cancer and first-line maintenance therapy for ovarian cancer with gBRCAm or sBRCAm, eligible patients had completed at least ONE course of platinum-based chemotherapy. In the pivotal trials for first-line maintenance therapy for ovarian cancer with gBRCAm or sBRCAm non-eligible

patients included: patients with early-stage disease (FIGO State I, IIA, IIB, or IIC) and patients with prior bevacizumab treatment. Subjects were randomized to treatment allocation within eight weeks after completion of the last dose of platinum-based chemotherapy. The intent is that treatment is started within a reasonable timeframe consistent with a maintenance treatment plan (i.e., as close to eight weeks as possible), to ensure the member is platinum-sensitive.

- PAOLA-1, the Phase 3 trial that studied olaparib (Lynparza) as dual therapy with bevacizumab for maintenance therapy for advanced ovarian cancer, was a double-blind, randomized, placebo-controlled trial with the primary endpoint of progression free survival (PFS). The primary endpoint results of the predefined subgroups of HRD-positive, HRD-negative, or unknown found only a statistically significant difference in PFS in the HRD-positive subjects (HR: 0.33, 95% CI: 0.25, 0.45) and not the HRD-negative or unknown patients (HR: 0.92, 95% CI: 0.72, 1.17). Subjects enrolled in the trial had Stage III or IV disease and had a successful response to prior taxane-based chemotherapy.
- The NCCN guideline for the treatment of ovarian cancers, recommends pathological staging followed by cytoreductive surgery as the preferred first-line treatment option for early-stage non-metastatic ovarian cancer. For patients who are poor candidates for surgery or have a low likelihood of optimal cytoreduction, a neoadjuvant systemic therapy (e.g., paclitaxel and platinum-based chemotherapy, bevacizumab) may be required. Similarly, these chemotherapy regimens may be applicable as adjuvant therapy following cytoreductive surgery (for stage II-IV disease). Post-primary treatment, a first-maintenance therapy with PARP inhibitors (e.g., niraparib, olaparib) may be utilized to extend remission. For a disease that recurs after first-maintenance, recurrence therapy with platinum-based chemotherapy regimens followed by a PARP inhibitor for maintenance (also known as recurrent maintenance) may be warranted. Use of olaparib (Lynparza) for recurrent-maintenance is recommended only for patients, who have not previously been treated with a PARP inhibitor.

IV. **Treatment of Breast Cancer:**

- OlympiA was a 12-month phase 3, double-blinded, randomized, placebo-controlled trial that investigated the use of olaparib in patients with early, high-risk, non-metastatic breast cancer with documented germline BRCA mutations (gBRCAm) that is predicted to be deleterious or suspected deleterious without disease progression after neoadjuvant or adjuvant treatment with anthracycline, taxane, or platinum agents. Additional oncology therapy was not permitted, but concomitant endocrine therapy was allowed. High-risk patients were defined by residual invasive disease after neoadjuvant therapy, or positive histopathological tests showing affected axillary or lymph nodes after adjuvant therapy. The primary end point was invasive disease-free survival (IDFS), defined as time to first invasive breast tumor, invasive disease, disease recurrence, second primary invasive cancer, or death from any cause. Three-year IDFS was present in 85.9% of the olaparib arm

and 77.1% in the placebo arm (HR = 0.58, [95% CI 0.41, 0.82], p=0.001). Overall survival was greater in the olaparib group by 32% compared to placebo (HR = 0.68, [98.5% CI 0.47-0.97], p=0.009). Distant disease–free survival was significantly longer among patients assigned to receive olaparib than placebo: 87.5% vs 80.4% (HR = 0.57, [99.5% CI, 0.39 to 0.83], P<0.001).

i. In line with the duration of the OlympiA trial, the FDA approved olaparib for treatment of HER2-negative high-risk, early breast cancer for up to 12 months, or until disease recurrence, or unacceptable toxicity. NCCN guidelines similarly recommend olaparib be used for up to 12 months.

ii. Since the publication of the OlympiA trial, capecitabine has been added as another guideline-directed adjuvant therapy option for HER2-negative, triple negative breast cancer (TNBC). Other guideline recommended adjuvant therapy options include olaparib (Lynparza) and pembrolizumab. Currently, there are no data to guide selection or sequencing of adjuvant therapy (olaparib or capecitabine) in HER2-negative TNBC. However, selection of therapy is based on patient specific factors (e.g., presence of gBRCAm for Lynparza). Current utilizers of capecitabine as an adjuvant therapy may be expected to transition to Lynparza based on presence of high-risk breast cancer, gBRCAm, and patient-specific factors including tolerability and toxicity. Additionally, the OlympiAD trial for metastatic breast cancer supported the efficacy of Lynparza versus chemotherapy (45% of patients received capecitabine) via improved surrogate outcomes of PFS.

- In the pivotal trial for breast cancer with metastatic, HER2-negative and gBRCAm, eligible patients had received neoadjuvant, adjuvant, or treatment for metastatic disease with an anthracycline (unless it was contraindicated) and a taxane. Approximately 70% of patients had received treatment in the metastatic setting; with 27% of patients having progressed after two lines of systemic therapies in the metastatic setting. 33% had no prior systemic therapy for metastatic disease. Eligible patients in this trial could have hormone-receptor positive metastatic breast cancer (i.e., estrogen-receptor positive, progesterone-receptor positive, or both) or triple negative metastatic breast cancer. Patients with hormone-receptor positive disease had received at least one endocrine therapy (adjuvant therapy or therapy for metastatic disease) and had disease progression during therapy, unless they had disease for which endocrine therapy was considered to be inappropriate.

V. **Treatment of Pancreatic Cancer:**

- The pivotal trial (POLO) is a Phase 3 trial that studied metastatic, gBRCAm pancreatic cancer; eligible patients had received a minimum of 16 weeks of first-line platinum-based chemotherapy (cisplatin, carboplatin, or oxaliplatin) and had not progressed while on the first-line platinum-based chemotherapy. The patients were randomized in a 3:2 ratio to receive maintenance olaparib (Lynparza) or placebo with the primary end point

progression-free survival. The median progression-free survival was statistically significant, 7.4 months in the olaparib (Lynparza) arm compared to 3.8 months in the placebo arm (HR 0.53 [95% CI, 0.35-0.81], p=0.0035). The interim analysis of overall survival showed no difference between groups (median, 18.9 months vs. 18.1 months; hazard ratio for death, 0.91; 95% CI, 0.56 to 1.46; P=0.68). Additionally, there was no significant between-group differences in health-related quality of life.

- Limited exception should be granted to those who do not meet the criteria for metastatic, gBRCAm pancreatic cancer as stated in this policy, given the current lack of data to support an improvement in survival or quality of life even in the evaluated population.
- The preferred systemic regimens for metastatic, gBRCAm pancreatic cancer include:
    i. FOLFIRINOX or modified FOLFIRINOX ± subsequent chemoradiation
    ii. Gemcitabine + albumin-bound paclitaxel ± subsequent chemoradiation

VI. **Treatment of Prostate Cancer:**

- PROfound, the Phase 3 trial that studied olaparib (Lynparza) in metastatic castration-resistant prostate cancer, enrolled men with homologous recombination repair (HRR) gene mutations in at least one of 15 prespecified HRR genes. Eligible patients had either a history of bilateral orchiectomy or were using luteinizing hormone-releasing hormone (LHRH) analog therapy and had progressed on enzalutamide or abiraterone acetate or both and were randomized (2:1) to receive either olaparib (Lynparza) or investigator's choice of enzalutamide or abiraterone acetate. Subjects were assigned cohorts based on HRR mutation (Cohort A: ATM, BRCA1, BRCA2; Cohort B: BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L). The primary endpoint was PFS in Cohort A and was significant between the treatment groups (HR: 0.34, 95% CI: 0.25, 0.47; p<0.001). Additionally, OS in Cohort A was significantly different between treatment groups (HR: 0.69, 95% CI: 0.50, 0.97; p=0.0175). PFS and OS were studied in Cohort B as exploratory endpoints and the results were not statistically significant and did not suggest improved outcomes with olaparib (Lynparza) over abiraterone or enzalutamide in those patients.
- In a randomized, double-blind, Phase 3 clinical trial (PROpel), the efficacy, safety, and tolerability of olaparib (Lynparza) was assessed versus placebo when given in addition to abiraterone in men with metastatic castration-resistant prostate cancer (mCRPC), who had not received prior chemotherapy or novel hormonal agents (NHAs; e.g., enzalutamide, apalutamide, abiraterone) in the 1st-line metastatic setting. Previous therapy with docetaxel in the neoadjuvant or adjuvant setting, as well as first-generation antiandrogen agents (e.g., bicalutamide, nilutamide) were permitted; however, were not required as part of the inclusion criteria. The primary endpoint, radiographic progression-free survival (rPFS), and secondary endpoints included OS and time to first subsequent anticancer therapy or death. In a predefined interim analysis (as of July 2022), olaparib (Lynparza) in combination with abiraterone reduced the risk of disease progression or death by 34% versus abiraterone alone (based on a hazard

ratio [HR] of 0.66; 95% confidence interval [CI] 0.54-0.81; p<0.0001). Median rPFS was 24.8 months for olaparib (Lynparza) plus abiraterone versus 16.6 months for abiraterone alone.

Investigational or Not Medically Necessary Uses

I. Early breast cancer with low to moderate-risk without metastasis, and/or HER2-positive, and/or breast cancer without gBRCAm, and/or use of Lynparza >1 year for early, high-risk breast cancer
   A. Safety and efficacy have only been established in patients with high-risk, non-metastatic HER2-negative, gBRCAm breast cancer treated with olaparib for a maximum duration of 12 months.

II. Pancreatic cancer without metastasis, and without gBRCAm
   A. The safety and efficacy of olaparib in the pancreatic cancer setting have only been established in patients with metastatic disease with gBRCAm who has not progressed on the first-line platinum-based chemotherapy.

III. Metastatic, gBRCAm pancreatic cancer that has progressed on first-line platinum-based chemotherapy
   A. The safety and efficacy of olaparib in the pancreatic cancer setting have only been established in patients with metastatic disease with gBRCAm who has not progressed on the first-line platinum-based chemotherapy.

IV. Use after disease progression on, or after, prior PARP inhibitor therapy
   A. There is no evidence to support the use of a subsequent PARP inhibitor following the progression of disease on another PARP inhibitor.

V. Metastatic castration-resistant prostate cancer with other tumor mutations (including BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L)
   A. The phase 3 trial PROfound studied olaparib (Lynparza) versus enzalutamide or abiraterone in Cohort A (ATM, BRCA1, BRCA2) and Cohort B (BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L). While statistically significant differences in PFS and overall survival (OS) were found in treatment with olaparib (Lynparza) in Cohort A and pooled Cohort A+B, the same was not found in Cohort B alone. Exploratory endpoints found PFS in Cohort B (HR: 0.88; 95% CI: 0.58, 1.36) and OS in Cohort B (HR: 0.73; 95% CI: 0.45, 1.23) not to be statistically significant and does not indicate improved patient outcomes with use of olaparib (Lynparza) over enzalutamide or abiraterone in these patients.

VI. Treatment of advanced ovarian cancer after 3 or more lines of therapy
   A. The manufacturer of olaparib (Lynparza) voluntarily withdrew the indication for treatment of adult patients with advanced ovarian cancer who have been treated with 3 or more prior chemotherapy regimens. This withdrawal was based on a totality of

information from PARP inhibitors in the late line treatment setting in ovarian cancer. Including, a subgroup analysis indicating a potential detrimental effect on overall survival (OS) for Lynparza compared to the chemotherapy control arm in the subgroup of patients who had received three or more prior lines of chemotherapy corresponding to the scope of the treatment indication for Lynparza in the randomized Phase III study, SOLO3 (NCT02282020).

B. SOLO3 was requested by the FDA to confirm the clinical benefit of Lynparza in the above indication. SOLO3 is a Phase III, open-label, randomized, controlled, multi-center study to assess the efficacy and safety of single agent Lynparza vs standard of care, based on physician's choice of single agent chemotherapy (i.e., weekly paclitaxel, topotecan, pegylated liposomal doxorubicin [PLD], or gemcitabine) in patients with platinum-sensitive relapsed (PSR) ovarian cancer who had received at least 2 prior lines of platinum-based chemotherapy, and who carried a germline deleterious or suspected deleterious breast cancer susceptibility gene (BRCA1/2) mutation. SOLO3 met its primary endpoint of ORR and the key secondary endpoint of progression-free survival (PFS). The final OS analysis subsequently occurred in 2021. In a OS subgroup analysis, a potential survival detriment was observed in the subgroup of patients treated with 3 or more prior lines of chemotherapy.

References

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Related Policies

Policies listed below may be related to the current policy. Related policies are identified based on similar indications, similar mechanisms of action, and/or if a drug in this policy is also referenced in the related policy.

Policy	Disease State
Cyclin-Dependent Kinase (CDK) 4/6 Inhibitors	Breast cancer
Talazoparib (Talzenna)	Breast cancer
Niraparib (Zejula)	Ovarian Cancer
Rucaparib (Rubraca)	Ovarian Cancer
Gonadotropin-releasing hormone (GnRH)	Advanced prostate cancer
	Advanced breast cancer in premenopausal women
	Reduction of endometrial thickness prior to endometrial ablation
	Gender dysphoria
	Central Precocious Puberty (CPP)
	Uterine leiomyoma (fibroids)
	Endometriosis
darolutamide (Nubeqa), apalutamide (Erleada), enzalutamide (Xtandi), abiraterone (Zytiga, Yonsa)	Prostate cancer

Policy Implementation/Update:

Action and Summary of Changes	Date
Removal of ovarian cancer indication in the late line (3+) treatment setting following voluntarily withdraw of the indication by the manufacturer. Added requirement of deleterious or suspected deleterious BRCA-mutated (BRCAm) for the treatment of mCRPC in combination with abiraterone.	09/2023
Added expanded indication for the treatment of mCRPC in combination with abiraterone; updated supporting evidence	06/2023
Defined castration resistant disease in setting of prostate cancer. Updated ovarian cancer criteria to align with FDA approved indications and to remove redundancies in coverage requirements; updated breast cancer criteria to remove requirement of 'no more than 2 therapies in metastatic setting'; updated supporting evidence	08/2022
Added new FDA expanded indication as an adjuvant therapy in early, high-risk, non-metastatic breast cancer. Combined criteria for metastatic and early, high-risk breast cancer. Updated investigational section and supporting evidence. Added criteria to disallow use after progression on another PARP inhibitor to align with other PARP inhibitor policies. Added renewal criteria to disallow combination therapy to align with initial criteria. Added related policies table.	06/2022

Included new FDA expanded indications as first-line maintenance therapy in advanced HRD-positive ovarian cancer in combination with bevacizumab and metastatic castration-resistant prostate cancer with certain HRR mutations. Supporting evidence has been included in the policy.	10/2020
Included new FDA expanded indication as first-line maintenance therapy in pancreatic adenocarcinoma with metastasis, gBRCAm, and patients whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. The criteria for approval in the pancreatic adenocarcinoma setting is to label, and the supporting evidence has been included in this policy. Advanced ovarian cancer without gBRCAm has been removed from the investigational and experimental section since olaparib (Lynparza) is approved in ovarian cancer without gBRCAm or sBRCAm. Pancreatic cancer without gBRCAm, and pancreatic cancer that has progressed on platinum-based chemotherapy have been added to the investigational and experimental section with supporting evidence. To improve clarity, for all the indications in this policy, the mutation documentation and the specific diagnoses have been separated out into individual criterion. Removal of toxicity question upon renewal as this is managed by the provider.	02/2020
Removal of DDID to reflect the most updated template version, removed the 8 weeks criterion around most recent platinum-based therapy in the setting of maintenance therapy in ovarian cancer; in place of the 8 weeks criterion, provider attestation and documentation is required instead.	12/2019
Criteria transitioned to policy format with the following additional updates: Included new FDA expanded indication as first-line maintenance therapy in ovarian cancer with gBRCAm or sBRCAm after complete or partial response to platinum-based chemotherapy. Additionally, a question was added to the renewal portion of this policy to assess for toxicity. Capsule formulation is no longer available; therefore, it has been removed from policy. Lastly, NCCN recognizes the term “deleterious” as pathogenic in the setting of gBRCAm OR sBRCAm; therefore, the policy has been updated to include the term “pathogenic” and “likely pathogenic” in parentheses next to the terms “deleterious” and “suspected deleterious” respectively.	03/2019
Criteria update: Added coverage criteria for ovarian cancer maintenance and metastatic breast cancer	02/2018